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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,017	01/17/2002	Kai Hua Wang		5595

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EXAMINER	
ZEMAN, ROBERT A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/050,017	WANG, KAI HUA	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *6-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election without traverse of Group I in the paper filed on 12-15-2003 is acknowledged. Claims 1-10 are pending. Claims 6-10 have been removed from consideration as being drawn to non-elected inventions. Claims 1-5 are currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification as filed does not reasonably provide enablement for any therapeutic composition comprising a biologically active polypeptide and a carrier fluid comprising components spleen extract, an emulsifier specific for the biologically active polypeptide, an immunogenicity suppression agent and an emulsion stabilizer.

The teachings of the specification cannot be extrapolated to the enablement of the claimed invention because the amount of guidance, direction, and exemplification is not reasonably commensurate with the claims. Moreover, the amount of guidance, direction, and exemplification set forth in the disclosure would be insufficient to enable the skilled artisan to

have a reasonable expectation of successfully making and using the claimed invention without having the need to perform an undue amount of experimentation.

Undue experimentation is a conclusion reached by weighing the noted factual considerations set forth below as seen in *In re* Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

The factors include, but are not limited to:

1. The breadth of the claims,
2. The nature of the invention,
3. The state of the prior art,
4. The level of one of ordinary skill,
5. The level of predictability in the art,
6. The amount of direction provided by the inventor,
7. The existence of working examples, and
8. The quantity of experimentation needed to make and/or use the invention based on the content of the disclosure.

The specification fails to provide sufficient guidance, direction or exemplification to enable the skilled artisan to make and use for a therapeutic composition comprising a biologically active polypeptide and a carrier fluid with the claimed components. Said components will be addressed individually below.

Biologically Active Agent:

With regard to the biologically active polypeptide, the claims encompass the much broader genus of a therapeutic composition comprising **any** biologically active polypeptide. Therefore, the claims encompass any and all biological molecules. However, the instant

disclosure is silent as to which molecules (other than G-CSF) would provide a benefit to a subject when administered orally to said subject. As illustrated by Lee et al. (U.S. Patent 5,362,424), orally administered "drugs" suffer from many problems including degradation in the stomach by the strongly acidic gastric juice and extensive hepatic first-pass metabolism (see column 1, lines 25-49). The specification is silent on what "biologically active polypeptides" would be susceptible to gastric degradation and/or first pass metabolism. It is equally silent on what "emulsifiers", if any, would be effective in reducing said susceptibilities for a given "biologically active polypeptide". Moreover, Rudnic et al. (U.S. Patent 5,897,876) disclose that the ability of "drugs" to be administered orally depends on several factors. The drug must be soluble in the gastrointestinal fluids in order for the drug to be transported across biological membranes or be suitable for an active transport mechanism. Rudnic et al. further disclose that small particulates can be absorbed through the lymphatic system (however, this method of absorption precludes absorbing large doses of drugs into systemic circulation) [see column 1, lines 8-16]. However, since the specification provides no guidance as to which "biologically active polypeptides" would be absorbed in concentrations high enough to be therapeutic to the subject, the skilled artisan would need to empirically determine whether members of the claimed genus of biologically active molecules would have provide the desired benefit when administered to a subject, and therefore, the skilled artisan could not make or use the invention with a reasonable expectation of success without having to perform an undue amount of experimentation.

Emulsifier

The specification is silent on what constitutes "an emulsifier specific for the biologically active polypeptide". The only "emulsifier" disclosed in the specification is lecithin. However, as exemplified by Wang et al. (U.S. Patent Publication US 2003/0068338 – see abstract) and Tabibi et al. (U.S. Patent 5,672,358 – see column 7. lines 19-25 and column 9, lines 25-30) lecithin is used to emulsify a myriad of active ingredients (i.e. is a non-specific emulsifier) and hence cannot be deemed "specific" for any biologically active polypeptide.

Immunogenicity Suppression Agent

The term "immunogenicity" is defined as:

> The property of being able to evoke an immune response within an organism. Immunogenicity depends partly upon the size of the substance in question and partly upon how unlike host molecules it is. Highly conserved proteins tend to have rather low immunogenicity (Dept. of Medical Oncology, University of Newcastle upon Tyne © Copyright 1997-2003 - The CancerWEB Project).

Therefore, by definition, an "immunogenicity suppression agent" is any agent that reduces the ability of a given agent to provoke an immune response in an organism. However, the specification is silent on what constitutes an "immunogenicity suppression agent". None of the working examples contain any component that could be construed as an "immunogenicity suppression agent". The compositions in the working examples consisted of G-SCF (biologically active agent), non-fat milk, lecithin (a generalized emulsifier); polyvinylpyrrolidone (a bulking agent); and optionally EDTA (a chelator). None of these components have been shown to act as an immunogenicity suppression agent. In fact, other than the biologically active polypeptide, none of the aforementioned components are considered to be immunogenic.

Polyvinylpyrrolidone (also known as povidone) is commonly used as a bulking agent in pharmaceuticals (see http://www.mercksource.com/pp/us/cns/cns_hl_dorlands.jspzQzpgzEzzSzppdocszSzuszSzcommonzSzdorlandszSzdorlandzSzdmd_p_31zPzhtm#1083482) and hence would not be immunogenic. EDTA is a chelating agent and like polyvinylpyrrolidone is used in compositions to protect substances from unwanted reactions.

Emulsion Stabilizers

Though not explicitly disclosed in the specification, emulsion stabilizers would encompass any substance that reduces or prevents destabilization of an emulsion. In working examples both EDTA and non-fat milk could be considered to be emulsion stabilizers.

In conclusion since the only working examples are limited to compositions comprising G-CSF (the biologically active polypeptide) and a carrier fluid wherein said carrier fluid comprises a spleen extract; non-fat milk; lecithin (an emulsifier); polyvinylpyrrolidone (a bulking agent); and optionally EDTA (a chelating agent), there is no correlation between the exemplified composition and the claimed invention. Additionally, the specification is silent what emulsifiers would be "specific" for a given biologically active polypeptide or what immunogenicity suppression agent would be successful in reducing the humoral and/or cellular response to a given biological agent while maintaining the ability of said agent to provide a "benefit" to the subject to which it is administered. Consequently, due to the lack of guidance

provided by the specification and the lack of working examples, the specification not enabling for the claimed invention.

As to claim 3, the claim is drawn to a vast genus of G-CSF analogs. This encompasses both structural and functional analogs. Protein chemistry is probably one of the most unpredictable areas of biotechnology Consequently, the effects of sequence dissimilarities upon protein structure and function cannot be predicted. Bowie et al (Science, 1990, 257:1306-1310) teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function and carry out the instructions of the genome and further teaches that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. (column 1, page 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (column 2, page 1306). The sensitivity of proteins to alterations of even a single amino acid in a sequence are exemplified by Burgess et al (J. of Cell Bio. 111:2129-2138, 1990) who teach that replacement of a single lysine reside at position 118 of acidic fibroblast growth factor by glutamic acid led to the substantial loss of heparin binding, receptor binding and biological activity of the protein and by Lazar et al. (Molecular and Cellular Biology, 1988, 8:1247-1252) who teach that in transforming growth factor alpha, replacement of aspartic acid at position 47 with alanine or asparagine did not affect biological activity while replacement with serine or glutamic acid sharply reduced the biological activity of the mitogen. These references demonstrate that even a single amino acid substitution will often dramatically affect the biological activity

and characteristics of a protein. Clearly, it would be impossible to predict which variant G-CSF proteins would maintain the characteristics of the wild-type G-CSF. Additionally, Bork (Genome Research, 2000,10:398-400) clearly teaches the pitfalls associated with comparative sequence analysis for predicting protein function because of the known error margins for high-throughput computational methods. Bork specifically teaches that computational sequence analysis is far from perfect, despite the fact that sequencing itself is highly automated and accurate (p. 398, column 1). One of the reasons for the inaccuracy is that the quality of data in public sequence databases is still insufficient. This is particularly true for data on protein function. Protein function is context dependent, and both molecular and cellular aspects have to be considered (p. 398, column 2). Conclusions from the comparison analysis are often stretched with regard to protein products (p. 398, column 3). Further, although gene annotation via sequence database searches is already a routine job, even here the error rate is considerable (p. 399, column 2). Most features predicted with an accuracy of greater than 70% are of structural nature and, at best, only indirectly imply a certain functionality (see legend for table 1, page 399). As more sequences are added and as errors accumulate and propagate it becomes more difficult to infer correct function from the many possibilities revealed by database search (p. 399, paragraph bridging columns 2 and 3). The reference finally cautions that although the current methods seem to capture important features and explain general trends, 30% of those features are missing or predicted wrongly. This has to be kept in mind when processing the results further (p. 400, paragraph bridging cols 1 and 2). Clearly, given not only the teachings of Bowie et al., Lazar et al. and Burgess et al. but also the limitations and pitfalls of using computational sequence analysis and the unknown effects of alternative splicing, post translational modification and cellular context on protein function as taught by Bork, the claimed protein analogs could not be predicted. Further, even if a given polypeptide possesses all the structural limitations of the claimed invention, neither the specification nor any art of record teaches what that polypeptide is, what it

does, does not teach a relationship to any specific disease or establish any involvement of the polypeptide in the etiology of any specific disease or teach which fragments might be active or which derivatives would function as claimed in a pharmaceutical composition. Clearly, it could not be predicted that a variant G-CSF protein (analog) that shares only partial homology with G-CSF will function in a given manner. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure how to make/use G-CSF analogs. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a vast genus of therapeutic compositions comprising, a biologically active polypeptide that provide a therapeutic benefit to a subject when administered to said subject, an emulsifier specific for said polypeptide, an immunogenicity suppression agent that reduces the humoral and/or cellular response to said polypeptide while preventing the inactivation of said polypeptide and an emulsion stabilizer. To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would

enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. To adequately describe the genus of therapeutic compositions, Applicant must adequately describe the biologically active polypeptides that provide a therapeutic benefit to a subject to which it is administered, the emulsifier specific for said polypeptide and the immunogenicity suppression agent effective for said polypeptide.

The specification does not disclose distinguishing and identifying features of a representative number of members of the genus of peptides to which the claims are drawn, such as a correlation between the structure of the biologically active polypeptide, the emulsifier or the immunogenicity suppression agent and their recited functions, so that the skilled artisan could immediately envision, or recognize at least a substantial number of members of the claimed genus of therapeutic compositions. Therefore, the specification fails to adequately describe at least a substantial number of members of the genus of biologically active polypeptides, emulsifiers or immunogenicity suppression agents to which the claims refer; and accordingly the specification fails to adequately describe at least a substantial number of members of the claimed genus of therapeutic compositions.

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

The Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description" Requirement (66 FR 1099-1111, January 5, 2001) state, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). Moreover, because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice commensurate in scope with the claimed invention has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to

show that Applicant were in possession of the claimed invention at the time the application was filed.

The *Guidelines* further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. It should be noted that therapeutic compositions comprising G-CSF (biologically active polypeptide) and a carrier fluid wherein said carrier fluid comprises a spleen extract with an optical density of 1.0 and a peak adsorption of 260 nm); non-fat milk; lecithin; polyvinylpyrrolidone; and optionally EDTA meet the aforementioned Written Description Requirements.

As to claim 3, the claim is drawn to a vast genus of G-CSF analogs. To fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention. The specification does not disclose distinguishing and identifying features of a representative number of members of the genus of analogs to which the claims are drawn so that the skilled artisan could immediately envision, or recognize at least a substantial number of

members of the claimed genus of therapeutic compositions. Therefore, the specification fails to adequately describe at least a substantial number of members of the genus of G-CSF analogs

MPEP § 2163.02 states, "[a]n objective standard for determining compliance with the written description requirement is, 'does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed' ". The courts have decided:

> The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the "written description" inquiry, *whatever is now claimed.*

See *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Federal Circuit, 1991). Furthermore, the written description provision of 35 USC § 112 is severable from its enablement provision; and adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

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reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant were in possession of the claimed invention at the time the application was filed.

The *Guidelines* further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the improper use of a period. It is unclear whether component "B" is meant to be include or excluded from the claimed invention since there is a period following the description of component "A". Proper claims are to be started

with a capital letter and ended with a period. It also should be noted that there is no period at the end of claim 1.

Claim 1 is rendered vague and indefinite by the use of the phrase "substances that are complimentary to said small molecule extract". It is unclear what is meant by said term. Moreover, it is unclear the basis on which "complementation" is determined. Consequently, it is impossible to determine the metes and bounds of the claimed invention.

Claim 1 is rendered vague and indefinite by the lack of units associated with the numerical value 14000. Since no units are recited it is impossible to determine the metes and bounds of the claim with regard to the recited molecular weight.

Claim 1 is rendered vague and indefinite by the use of the phrase "having an average molecular weight of about 14,000 or less". It is unclear what is meant by said phrase. How can one have an average molecular weight of 14,000 when 14,000 is the molecular weight cutoff? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claims 1 is rendered vague are rendered vague and indefinite by the term "biologically active". It is unclear what is meant by said term. What biological activities are encompassed by said term? How are said activities measured? What threshold is used to discern between "active" and "inactive" polypeptides?

Claim 1 recites the limitation "the suspension" in line 18. There is insufficient antecedent basis for this limitation in the claim.

Conclusion

No claim is allowed.

All claims are free of the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (571) 272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia A. Duffy.
PATRICIA A. DUFFY
PRIMARY EXAMINER

Robert A. Zeman
March 2, 2004